



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/940,235 | 08/27/2001 | Girish Sahni | 07064-009002 | 5356 |
| 26161 | 7590 | 12/16/2004 | EXAMINER | |
| FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110 | | | SWOPE, SHERIDAN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,235

Applicant(s)

SAHNI ET AL.

Examiner

Sheridan L. Swope

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,32 and 33 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3,32 and 33 is/are rejected.
7) ☐ Claim(s) 3, 33 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Art Unit: 1652

DETAILED ACTION

Applicant's response, of September 22, 2004, to the action on the merits of this case, mailed March 19, 2004, is acknowledged. It is acknowledged that applicants have amended Claims 1, 2, and 32 and added Claim 33. Claims 1, 3, 32, and 33 are pending and are hereby considered.

Claim-Objection

Claim 3 is objected to for "rages" on line 2, which should be corrected to "ranges".

Claim 33 is objected to for "SEQ ID NO2" on line 2, which should be "SEQ ID NO: 2".

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 5-6, and Claim 33, line 2-3, in reciting "a least one the fibronectin finger-type fibrin binding domain (FBD) pairs 1-2 or 4-5" are confusing. Do Applicants mean to recite "a least one of the fibronectin finger-type fibrin binding domain (FBD) pairs of either 1 and 2 or 4 and 5"? Clarification is required.

Claim 33 recites "fibronectin finger-type binding domain (FBD) pairs 1-2 or 4-5 of SEQ ID NO: 4. Neither the claims nor the specification clearly define which residues of SEQ ID NO: 4 are fibronectin finger-type binding domain pairs 1-2 and 4-5 and, thus, one of skill in the art

would not know the metes and bounds of the recited invention. Therefore, Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claim Rejections - 35 USC § 112-First Paragraph

Enablement

Rejection of Claims 1, 3, and 32 under 35 USC § 112-First Paragraph, for lack of enablement for the full scope of the recited invention, for the reasons described in the prior action, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. That streptokinase is a well-studied, rather thoroughly-studied, protein; its three-dimensional structure is known. That, streptokinase from various species have high structural homology. That, "The sole criterion for selection, as is abundantly clear from the specification (particularly where the rationale for the designs is explained), is that the selected streptokinase fragments should display a plasminogen activator ability to begin with (that is, prior to fusion), which then becomes reversibly attenuated as a result of the fusion with fibronectin binding domains." Assays to test for plasminogen activator ability are known in the art. That, fibrin binding domains from proteins such as fibronectin etc belong to a small family of "finger" type FBDs with highly conserved sequence, structure, and function that would easily allow successful construction of the chimeric proteins recited.

These arguments are not found to be persuasive for the following reasons. It is acknowledged that streptokinase is a well-studied protein. However, to enable a person of ordinary skill in the art to make and use the recited invention, the claims must recite both the structural and functional limitations of the recited proteins. Claims 1 and 3 fail to provide any

Art Unit: 1652

structural limitation for the recited fusion proteins, thus a person of skill would not know how to make the recited invention. To make and screen essentially any protein with any structure for plasminogen activator and fibrin binding activities is clearly undue experimentation.

Therefore, rejection of Claims 1, 3, and 32 for lack of enablement, for the reasons described in the prior action, is maintained.

Written Description

Rejection of Claims 1, 3, and 32 under 35 USC § 112-First Paragraph, for insufficient Written Description, as described in the prior action, is maintained. Applicants did not specifically respond to said rejection. However, as stated above, the claims do not provide any structural limitations for the recited proteins and, therefore, said proteins are not sufficiently described.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Sheridan Lee Swope, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
16 00